

REMARKS

Claims 29-52, 54-55, 57 and 59-73 are pending in the application with entry of this amendment. Claim 58 is canceled without prejudice. Claims 29, 57 and 67 are currently amended. The claim amendments do not introduce new matter. *See, e.g.*, original claim 58 (reciting “insulative member”); Fig. 2 (insulative member 150 positioned between temporary connection 130 and implant 140). The subject application also explains that the catheter 110 and insulative member 150 form an “insulative chamber” that prevents or minimizes the amount of current that flows through the delivery member 120 when the delivery member 120 is confined to the lumen 112 of the catheter 110. Reconsideration and allowance of the application, as amended, are respectfully requested.

I. Withdrawn Rejections

Applicants kindly acknowledge that the rejection of claims 29-36, 44-46, 54, 55, 57-61, 64 and 65 under 35 U.S.C. §102(b) as being allegedly anticipated by U.S. Patent No. 5,669,905 to Scheldrup *et al.* (“Scheldrup”) has been withdrawn. The Final Office Action includes new grounds of rejection under 35 U.S.C. §103(a) based on a combination of references including a new reference, U.S. Patent No. 6,238,340 to Alt (“Alt”).

II. Claims 29-36, 44-46, 54, 55, 57, 59-61, 64, 65 and 72 Are Patentable Over Scheldrup and Alt

Independent claim 29 and dependent claims 30-36, 44-46, 54, 55, 57, 59-61, 64, 65 and 72 stand rejected under 35 U.S.C. §103(a) as being allegedly being unpatentable or obvious over Scheldrup in view of Alt. To properly establish a *prima facie* case of obviousness of a claim under 35 U.S.C. §103(a), all the claim limitations must be taught or suggested by the prior art, and all words in a claim must be considered in judging the patentability of that claim against the prior art. MPEP §2143.03. Moreover, there must be a reason to combine or modify the cited references. Further, if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. MPEP §2143.01. Similarly, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima*

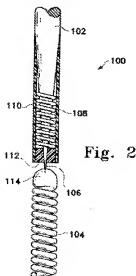
facie obvious. MPEP §2143.01. It is also improper to combine references where the references teach away from their combination. MPEP §§2141.02 and 2145.

Applicants respectfully traverse the rejection since the cited references, individually and even if somehow properly combined, fail to disclose, teach or suggest each limitation of each rejected claim. Moreover, a person of ordinary skill in the art would not combine the cited references given their substantially different structural configurations and functionality, the required modifications that would be necessary, and since certain references teach away from various claims.

Claim 29 is currently amended to recite *inter alia* “an insulative member” (as recited in original 58), “a temporary connection joined to a distal end of the delivery member, the insulative member being positioned between and connecting the temporary connection and the implant” and “the temporary connection is joined to the delivery member and joined to the implant through the insulative member”.

With regard to claim 29 as amended, it is conceded that “Schledrup does not disclose an insulation member between the implant and the temporary connection”. Final Office Action (p. 5). Instead, it is generally alleged that it would have been obvious configure an insulation member, an implant and a temporary connection in this manner. The cited references, however, do not disclose or otherwise suggest or imply such a configuration, and do not support this general, unsupported conclusion, particularly in view of the specific structure described by Schledrup.

FIG. 2 of Schledrup is reproduced below for reference:



As explained by Scheldrup, and as shown in FIG. 2 above, the guide wire 102 tapers at its distal end to a point, which is soldered into the proximal end of an occlusion device 104. The guide wire 102 is covered with an insulating material except for the most distal exposed joint or sacrificial link 106. Scheldrup (col. 5, lines 40-49; FIG. 2). Scheldrup further explains that on the distal tip of the core wire 102 may be found a pair of insulators (sleeve 110 and end plug 112) that serve to further remove the stainless steel coil 108 from contact with the blood while electrolytic detachment is performed. FIG. 2 of Scheldrup shows the distal end of the guide wire 102 extending completely through the end plug 112, and the sacrificial link 106 being connected directly to a solder joint 114, which forms the proximal end of the occlusion device 104.

Accordingly, Scheldrup describes a specific structural configuration in which there is no insulation element positioned between the sacrificial link 106 and the solder joint 114 of the occlusion device 104 since the sacrificial link 106 is the distal, pointed end of the guide wire 102, which extends completely through and past the end plug 112 such that a direct connection can be made to the solder joint 114 of the proximal end of the device 104. Consequently, Scheldrup does not disclose, teach or suggest “the insulative member being positioned between and connecting the temporary connection and the implant” and “the temporary connection is joined to the delivery member and joined to the implant through the insulative member” as recited in claim 29 as amended. Moreover, the Office Action has not established why it would be obvious to substantially modify the particular structural configuration shown in FIG. 2 of Scheldrup into a different configuration in which an insulation member is positioned between and connects a temporary connection and an implant, particularly considering that the sacrificial link 106 is the distal, pointed end of the guide wire 102, there is a direct electrical connection to the solder joint 114 (the proximal end of the vaso-occlusive device), and for this purpose, the distal portion or point of the guide wire 102 extends completely through the end plug 112.

Additionally, it is conceded that Scheldrup fails to disclose that the temporary connection must be joined to the implant while the electrical output signal is generated by the electrical measurement device. Final Office Action (p. 3). As noted in the previous Amendment (and not repeated here), various sections of Scheldrup describe detecting detachment of a coil by breaking of a temporary connection and indicating a change in an electrical condition that results from or follows breaking of the temporary connection. Scheldrup (Abstract; col. 1, line 17; col. 3, lines 5, 18-21, 60-63, 66-67; col. 4, lines 12-18, 34; col. 7, lines 61-62; col. 8, lines 25-26, 53; col. 8, line 67 - Col. 9, line 5; col. 11, lines 55-57, 65-67).

It is stated in the Final Office Action that Scheldrup discloses that the device is capable of detecting a condition that may not be a result of dissolution of the temporary connection. Final Office Action (p. 3, citing Scheldrup, col. 4, lines 24-33). However, it is Applicants' understanding that the cited section of Scheldrup describes criteria for interrupting DC power that is supplied to minimize or avoid **post detachment** electrolysis. More specifically, in the paragraph immediately preceding the cited col. 4, lines 24-33, Scheldrup explains:

According to another aspect of the invention, the DC power supply to the sacrificial link is interrupted when a sudden change in the monitored AC impedance occurs. In this manner, **post detachment electrolysis of the linking member is minimized or avoided**. Scheldrup (col. 4, lines 19-23) (emphasis added).

The very next paragraph (col. 4, lines 24-33) (cited by the Final Office Action) appears to describe how impedance is monitored and compared relative to an average value to determine when to interrupt the DC power supply to minimize or avoid electrolysis **after** detachment (as discussed in the preceding paragraph). In particular, Scheldrup explains:

According to a particular embodiment of the invention, the **impedance** (as **measured by the amplitude of the AC signal**) is averaged over time. When a change from the averaged value in excess of 20% is detected, the power input to the sacrificial link is shut off. Changes below this value may be caused by factors other than dissolution of the linking member, which would result in a false indication of detachment. On the other hand, a system that requires more than 40% change may not detect all detachments. Scheldrup (col. 4, lines 24-33) (emphasis added).

Thus, Scheldrup explains that when a measured impedance value is higher than 20% of the average impedance value, power is shut off to minimize or avoid **post detachment** electrolysis, and impedance levels below this level may be caused by other facts resulting in a false detachment indication. The particular reason impedance is monitored, and the otherwise limited description of false detachment indications, do not amount to disclosing, teaching or suggesting "an electrical measurement device" that is configured to (i) "monitor an electrical condition related to a position of the temporary connection while the temporary connection is joined to the implant and delivery member, the electrical condition changing when the temporary connection, joined to the implant, reaches a predetermined location as the delivery member is advanced through the catheter," and (ii) "generate an output signal while the temporary connection is joined to the implant and in response to the changed electrical condition, the output signal

indicating that the temporary connection, joined to the implant, has reached the predetermined location” (*i.e.*, before the temporary connection is broken), as recited in claim 29.

Applicants also note that the Final Office Action apparently no longer alleges that col. 7, line 49 - col. 8, line 33 of Scheldrup discloses indicating that a temporary connection is at a predetermined site before separation has occurred. *See*, April 4, 2007 Office Action (p. 10, para. 9). As discussed in Applicants’ prior Amendment, Scheldrup describes, among other things, determining that a coil detachment has occurred, and then, using a detach indicator (such as a light) to indicate that detachment has already occurred. Scheldrup (col. 8, lines 29-30) (emphasis added). This section also refers to a “Pause Mode” when electrolytic separation has occurred. Scheldrup (col. 7, lines 61-62) (emphasis added).

The Office Action relies on Alt as allegedly disclosing a connection 15 that contacts body tissue or fluids, and an electrical signal that is sensed while the connection is joined to the implant, and alleges that it would be obvious to provide an output signal while still being connected to the implant, as taught by Alt. Applicants respectfully disagree and note a number of inaccuracies with the manner in which Alt is characterized and applied.

Initially, it is alleged that Alt describes a device “10” and that element “15” is a “connection”. Final Office Action (p. 3). Alt, however, actually explains a catheter 10 that is to be inserted within a patient with the aid of x-ray fluoroscopy includes an elongate body 12 and “one or more exposed metallic surfaces consisting of metal bands 15.” Alt (col. 4, lines 29-38). The purpose of these metallic surfaces 15 is to “enable physician viewing of the metal surface(s) of band(s) 15, which by virtue of its metal composition, is visible as a shadow on the fluoroscope...” Alt (col. 4, lines 59-61). A biocompatible material 25 is applied to the metallic surface 15 to reduce secondary enhancement effects. Alt (col. 5, lines 3-10, 25-43).

Thus, as described by Alt, the metallic surface 15 is not a “connection” as alleged in the Office Action. Further, it is not clear how an integral “surface” of an object can be a “connection” as recited in claim 29. The Office Action allegation is not consistent with the ordinary meanings of these terms, particularly in the context in which they are used by persons of ordinary skill in the art and the description of a “surface 15” in Alt. Nevertheless, the metallic surface 15 certainly is not “a temporary connection” and does not join an implant and a distal end of the delivery member as recited in claim 29.

Further, a person of ordinary skill in the art would not combine the cited references in view of the substantial structural and functional differences for use in different applications and

to achieve very different results. Scheldrup is specifically directed to disintegrating a stainless steel sacrificial link to electrolytically detach an implant. Understandably, Scheldrup is not at all related to using a sacrificial link to monitor the location of a catheter using fluoroscopy. Alt, on the other hand, is specifically directed to using a metallic surface 15 in connection with fluoroscopy and, understandably, is not at all related to electrolytic detachment of an implant by electrically detaching the surface 15 since the surface 15, as is well understood, is an integral and necessary part of the catheter 10. Further, in Scheldrup, a metal component or electrolytic link is destroyed, whereas in Alt, the metal surface 15 is a necessary and integral component of a catheter device and cannot be disintegrated. Nowhere does Alt explain or remotely imply that these surfaces 15 are destroyed or disintegrated. Thus, Scheldrup and Alt are not only unrelated to each other, but the metal components are used in very different ways for very different purposes and, therefore, a person of ordinary skill in the art would not combine these references.

Moreover, using the metallic surface 15 for electrolytic detachment as alleged by the Final Office Action would result in disintegration of the metallic surface 15, but the metallic surface 15 is a permanent, integral and critical component of the device. Thus, the Office action allegations essentially result in destruction of the metallic surface 15, thereby rendering the metallic surface 15 unsatisfactory for its intended purpose and contrary to the intended principle of operation of device described by Alt. As discussed above, the metallic surface is used for fluoroscopic viewing and for receiving a biocompatible material 25 to reduce secondary enhancement effects and is not designed to be destroyed.

In addition to these significant differences, Alt also teaches away from “a temporary connection” as recited in claim 29 and teaches away from the alleged modifications and combination with Scheldrup as alleged in the Final Office Action since the metallic surface 15 is a permanent and integral part of the catheter 10, not temporary, and not a temporary connection.

Moreover, Scheldrup teaches away from claim 29 since Scheldrup is directed to detecting a change of impedance after coil detachment and, therefore, describes a configuration that is the opposite of that recited in claim 29, which recites *inter alia* “the electrical condition changing when the temporary connection, joined to the implant, reaches a predetermined location” and “while the temporary connection is joined to the implant.” Scheldrup (Abstract; col. 1, line 17; col. 3, lines 5, 18-21, 60-63, 66-67; col. 4, lines 12-18, 34; col. 7, lines 61-62; col. 8, lines 25-26, 53; col. 8, line 67 - col. 9, line 5; col. 11, lines 55-57, 65-67).

Further, Scheldrup teaches away from “a temporary connection joined to a distal end of the delivery member, the insulative member joining and being positioned between the temporary connection and the implant” and “the temporary connection is joined to the delivery member and to the implant through the insulative member” as recited in claim 29 in view of the particular structural configuration described by Scheldrup, *e.g.*, the pointed distal end of the guide wire 102 extending completely through the end plug 112, and the sacrificial link 106 being connected directly to a solder joint 114, which forms the proximal end of the occlusion device 104.

In view of these substantial deficiencies and differences, Applicants respectfully submit that independent claim 29 is patentable over Scheldrup and Alt. Dependent claims 30-36, 44-46, 54, 55, 57, 59-61, 64, 65 and 72 depend from and incorporate all of the elements and limitations of independent claim 29, and are therefore also believed patentable over Scheldrup and Alt for the same reasons above. MPEP §2143.03 (If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious).

Further, Scheldrup fails to disclose, teach or suggest “a visual indicator, the electrical measurement device being configured to provide the output signal to the visual indicator so that the visual indicator can be illuminated after the electrical condition has changed while the implant is joined to the temporary connection” as recited in claim 54. In contrast, Scheldrup describes a LED that flashes after detecting a coil detachment, *i.e.*, not while the implant is joined to the temporary connection. Scheldrup (col. 8, lines 29-30).

Scheldrup also fails to disclose, teach or suggest “an audio indicator, the electrical measurement device being configured to provide the output signal to the audio indicator so that the audio indicator can be activated after the electrical condition has changed while the implant is joined to the temporary connection” as recited in claim 55. Rather, while Scheldrup may disclose emitting beeps, these beeps are emitted after coil detachment has already occurred, *i.e.*, not while the implant is joined to the temporary connection. Scheldrup (col. 10, lines 33-34).

Still further, Scheldrup fails to disclose or suggest “a controller, the electrical measurement device being configured to provide the output signal to the controller while the implant is joined to the temporary connection, the controller being configured to automatically break the temporary connection in response to the output signal after the electrical condition has changed” as recited in claim 57. Instead, as discussed above, Scheldrup explains that the impedance changes as a result of or after coil detachment has already occurred, *i.e.*, not while the implant is joined to the temporary connection.

Scheldrup also fails to disclose, teach or suggest claims 59-61, which recite limitations related to changes in electrical condition based on a location of a temporary connection relative to a distal end of a catheter and when the temporary connection reaches or passes the distal end of the catheter. Claim 61 was amended to recite *inter alia* “the electrical condition changing when the temporary connection, while joined to the implant, extends beyond the distal end of the catheter.” In contrast, Scheldrup explains that the change of impedance occurs after, or as a result of, detachment of a coil (*i.e.*, dissolving of sacrificial link 106).

Scheldrup also fails to disclose, teach or suggest claim 64, which was also amended to recite “related to a position of the temporary connection, while joined to the implant.”

Accordingly, Applicants respectfully submit that claims 29-36, 44-46, 54, 55, 57, 59-61, 64, 65 and 72 are patentable over Scheldrup and Alt and respectfully request that the rejection under 35 U.S.C. §103 be withdrawn.

III. Claim 37 Is Patentable Over Scheldrup, Alt and Palermo

Dependent claim 37 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Scheldrup in view of Alt, and further in view of U.S. Patent No. 5,250,071 to Palermo (“Palermo”). Palermo is cited for the limited purpose of allegedly disclosing a temporary mechanical connection. Palermo, however, does not cure the substantial deficiencies of Scheldrup and Alt with respect to independent claim 29 as discussed above. Consequently, even if the alleged combination were somehow made, the combination would nevertheless fail to disclose each and every limitation of claims 29 and 37.

Moreover, a person of ordinary skill in the art would not combine the references as alleged in the Final Office Action given the substantially different structural configurations and functionality of components of the references. Scheldrup and Palermo are related to releasing a vaso-occlusive or embolic device, but Scheldrup involves sacrificial electrolytic links, not mechanical links, and Alt describes a metallic surface or band 15 that generates a visible shadow on a fluoroscope and is configured to receive a biocompatible material to reduce secondary enhancement effects. Alt (col. 4, lines 59-61; col. 5, lines 5-43). Alt is not related to releasing an implant, and certainly is not related to temporary mechanical connections.

Alt also teaches away from temporary mechanical connections since the metallic surface or band 15 is a permanent, critical and integral part of the catheter 10, and also teaches away from the alleged modifications and combination of references. Scheldrup also teaches away

from claim 29 since Scheldrup is directed to detecting a change of impedance following, or resulting from, detachment of a coil and, therefore, describes a configuration that is the opposite of that recited in claim 29. Scheldrup (Abstract; col. 1, line 17; col. 3, lines 5, 18-21, 60-63, 66-67; col. 4, lines 12-18, 34; col. 7, lines 61-62; col. 8, lines 25-26, 53; col. 8, line 67 - col. 9, line 5; col. 11, lines 55-57, 65-67).

Dependent claim 37, therefore, is also believed patentable over Scheldrup, Alt and Palermo.

IV. Claims 38 and 39 Are Patentable Over Scheldrup, Alt and Guglielmi

Dependent claims 38 and 39 are rejected under 35 U.S.C. §103(a) as being unpatentable over Scheldrup and Alt and further in view of U.S. Patent No. 5,569,245 to Guglielmi *et al.* ("Guglielmi"). Guglielmi is cited for the limited purpose of allegedly disclosing temporary connections broken by heat and RF radiation. Guglielmi, however, does not cure the deficiencies of Scheldrup and Alt with respect to independent claim 29. Accordingly, even if the alleged combination were made, the combination would fail to disclose each and every limitation of claims 29, 38 and 39.

Moreover, a person of ordinary skill in the art would not combine the references as alleged in the Final Office Action given the substantially different structural configurations and functionality of components of the cited references. Scheldrup and Guglielmi are related to releasing a vaso-occlusive or embolic device, but Alt describes a metallic surface or band 15 that generates a visible shadow on a fluoroscope and is configured to receive a biocompatible material to reduce secondary enhancement effects. Alt (col. 4, lines 59-61; col. 5, lines 5-43). Alt is not related to releasing an implant, and certainly is not related to temporary connection breakable by heat or RF radiation.

Alt also teaches away from such breakable and temporary devices since the metallic surface or band 15 is a permanent, critical and integral part of the catheter 10, and further teaches away from the alleged modifications and combination of cited references. Scheldrup also teaches away from claim 29 since Scheldrup is directed to detecting a change of impedance following, or resulting from, detachment of a coil and, therefore, describes a configuration that is the opposite of that recited in claim 29. Scheldrup (Abstract; col. 1, line 17; col. 3, lines 5, 18-21, 60-63, 66-67; col. 4, lines 12-18, 34; col. 7, lines 61-62; col. 8, lines 25-26, 53; col. 8, line 67 - col. 9, line 5; col. 11, lines 55-57, 65-67).

Dependent claims 38 and 39, therefore, are also believed patentable over Scheldrup, Alt and Gugliemi.

V. Claim 40 Is Patentable Over Scheldrup, Alt and Sepetka

Dependent claim 40 is rejected under 35 U.S.C. §103(a) as being unpatentable over Scheldrup and Alt and further in view of U.S. Patent No. 5,814,062 to Sepetka *et al.* ("Sepetka"). Sepetka is cited for the limited purpose of allegedly disclosing a connection that is hydraulically broken. Sepetka, however, does not cure the deficiencies of Scheldrup and Alt with respect to independent claim 29. Accordingly, even if the alleged combination were made, the combination would fail to disclose each and every limitation of claims 29 and 40.

Moreover, a person of ordinary skill in the art would not combine the references as alleged in the Final Office Action given the substantially different structural configurations and functionality of components of the cited references. Scheldrup and Sepetka are related to releasing a vaso-occlusive or embolic device, but Scheldrup involves sacrificial electrolytic links, not temporary connections that are hydraulically breakable, and Alt describes a metallic surface or band 15 that generates a visible shadow on a fluoroscope and is configured to receive a biocompatible material to reduce secondary enhancement effects. Alt (col. 4, lines 59-61; col. 5, lines 5-43). Alt is not related to releasing an implant, and certainly is not related to temporary connections that are hydraulically breakable.

Alt also teaches away from such hydraulically breakable and temporary devices since the metallic surface or band 15 is a permanent, critical and integral part of the catheter 10 and teaches away from the alleged modifications and combination of cited references. Scheldrup also teaches away from claim 29 since Scheldrup is directed to detecting a change of impedance following, or resulting from, detachment of a coil and, therefore, describes a configuration that is the opposite of that recited in claim 29. Scheldrup (Abstract; col. 1, line 17; col. 3, lines 5, 18-21, 60-63, 66-67; col. 4, lines 12-18, 34; col. 7, lines 61-62; col. 8, lines 25-26, 53; col. 8, line 67 - col. 9, line 5; col. 11, lines 55-57, 65-67).

Dependent claim 40, therefore, is also believed patentable over Scheldrup and Sepetka.

VI. Claims 41-43 and 47-52 Are Patentable Over Scheldrup and Alt

Dependent claims 41-43 and 47-52 are rejected under 35 U.S.C. §103(a) as being unpatentable over Scheldrup and Alt as applied to claim 29. Applicants respectfully submit that

the rejection of dependent claims 41-43 and 47-52 under §103(a) is moot in view of the remarks concerning Scheldrup and Alt above.

Dependent claims 41-43 and 47-52, therefore, are also believed patentable over Scheldrup and Alt. MPEP §2143.03.

VII. Claims 62, 63 and 67-71 Are Patentable Over Scheldrup, Alt and Cheng

Independent claim 67, dependent claims 62 and 63 (which depend from claim 29) and dependent claims 68-71 (which depend from claim 67) are rejected under 35 U.S.C. §103(a) as being unpatentable over Scheldrup and Alt and further in view of U.S. Patent No. 6,296,636 to Cheng *et al.* ("Cheng"). Cheng is cited for the limited purpose of allegedly disclosing a comparison circuit that compares a threshold current to a current measured by an electrical measurement device.

Cheng, however, does not cure the deficiencies of Scheldrup and Alt with respect to independent claim 29. Therefore, dependent claims 62 and 63 are believed patentable.

Further, the cited references, individually and in combination, fail to disclose, teach or suggest all of the limitations of independent claim 67 (and, thus, by extension), dependent claims 68-71. For example, the cited references, individually and in combination, fail to disclose, teach or suggest a current measurement device configured to monitor the electrical current as the delivery member is pushed through the catheter, the electrical current being related to a relative position of the temporary connection before the temporary connection is broken, the electrical current increasing from a first current level while the temporary connection is joined to the implant, to a second, higher current level when the temporary connection, joined to the implant, reaches a predetermined location relative to the catheter as required by claim 67. Accordingly, even if the alleged combination were made, the combination would fail to disclose each and every limitation of claim 67. Thus, Applicants respectfully submit that the rejection of dependent claim 67 under §103(a) cannot stand. MPEP §2143.03.

Further, Applicants respectfully submit that a person of ordinary skill in the art would not combine Scheldrup and Alt as discussed in detail above. Further, Cheng is directed to ablation or coagulation of tissue and limiting the amount of power delivered during electrosurgery, whereas Scheldrup is related to methods for ensuring endovascular occlusion. (*Cf.* Cheng, col. 3, lines 48-55; Scheldrup, Abstract). Moreover, while Cheng describes a device for ablation or coagulation, the metallic surface or band 15 of Alt is used for purposes of fluoroscopy. The

substantial structural and functional differences of such devices are well understood by persons of ordinary skill in the art, who would no combine the references in view of such differences.

Claims 62, 63 and 67-71, therefore, are believed patentable over Scheldrup, Alt and Cheng.

CONCLUSION

Applicants respectfully submit that the application is in condition for allowance in view of the forgoing amendments and remarks. If there are any remaining issues that can be resolved by telephone, Applicants invite the Examiner to contact the undersigned at the number indicated below.

Respectfully submitted,

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